K072739
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510(k) Summary

MAR 21 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: _____

1. Applicant Device Information

Trade/Proprietary Name: Jierui Syringes and Needle

Classification Information:

a. Sterile Hypodermic Syringe for single use, with/without needle

(1) Classification Name: Syringe, Piston
(2) Regulation Number: 880.5860
(3) Product Code: FMF
(4) Class: II
(5) Review Panel: General Hospital

b. Retractable Auto-Disable Syringe for single use, with/without needle

(1) Classification Name: Syringe, Antistick
(2) Regulation Number: 880.5860
(3) Product Code: MEG
(4) Class: II
(5) Review Panel: General Hospital

c. Sterile Insulin Syringe for single use, with fixed needle

(1) Classification Name: Syringe, Piston
(2) Regulation Number: 880.5860
(3) Product Code: FMF
(4) Class: II
(5) Review Panel: General Hospital

d. Sterile Hypodermic Needle for single use

(1) Classification Name: Needle, Hypodermic, Single Lumen
(2) Regulation Number: 880.5570
(3) Product Code: FMI
(4) Class: II
(5) Review Panel: General Hospital

2. Submitter Information

Manufacturer Name:

ShanDong WeiGao Group Medical Polymer Products Co., LTD
No.312, Shichang Road
Weihai, Shandong, China, 264209

Contact Person of the Submission:

Ms. Diana. Hong
Mr. Eric. Chen
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, China 20030
Phone: +86-21-64264467 x 152
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Email: Diana.hong@mid-link.net
Eric.chen@mid-link.net

3. Predicate Device

a. **K number: K070936**
Trade Name: Welmed Hypodermic Syringe (various sizes)
Common Name: Syringes, Hypodermic
Classification Name: Piston Syringe
Product Code: FMF

b. **K number: K071630**
Trade Name: TERUMO 31G ThinPro Insulin Syringe
Classification Name: Piston syringe with fixed hypodermic single lumen needle
Product Code: FMF

c. **K number: K053519**
Trade Name: Safety Syringe
Common Name: Syringe
Classification Name: Syringe,Antistick
Product Code: MEG

d. **K number: K070440**
Trade Name: BD Hypoint
Common Name: Hypodermic Needle
Classification Name: Single Lumen Hypodermic Needle
Product Code: FMI

4. Device Description

Device Name	Intended Use	Nozzel	Volume	Material	Remark
Sterile Hypodermic Syringe for single use	The Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Luer Slip	1,2,3,5,10,20,30,50,100 (ml)	PP	With or Without Needle
		Luer Lock	3,5,10,20,50,100 (ml)		
Sterile Insulin Syringe for single use	The sterile Insulin Syringe for single use with needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.	Fixed	0.5,1 (ml)	PP	With Fixed Needle
Retractable Auto-Disable Syringe for single use	The Retractable Auto-Disable Syringe for single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.	Luer Lock	3,5,10 (ml)	PP	With or Without Needle
Sterile Hypodermic Needle for single use	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration	Luer Slip Luer Lock	16G,18G,19G,20G, 21G,22G,23G,24G, 25G,26G,27G,29G	Stainless Steel	--

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5. Substantially Equivalence Determination

Comparison Analysis:

The Applicant device has the same classification information, intended use, sterilization specifications, performance, biocompatibility, chemical specifications and similar physical and mechanical specifications with the predicate device. The only difference between applicant device and predicate device is some physical specifications variant which is too slight to influence the effectiveness and safety.

Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

6. Effectiveness and Safety Considerations

Effectiveness:

All the variant models of the applicant device are evaluated regarding the performance.

Safety Considerations:

With accordance with the Table 1 Initial Evaluation Tests for Consideration and Table 2 Supplementary Evaluation Tests for Consideration in ISO 10993-1:2003(E), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing, the necessary tests for Biocompatibility Testing includes: Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Systemic Toxicity (Acute), Haemo-compatibility.

Conclusion: The all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of all the possible skin-contact component material in the finished product meets the requirement of Biocompatibility

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2008

ShanDong WeiGao Group Medical Polymer Products Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, No. 19, Lane 999
Zhongshan No. 2 Road (S)
Shanghai 200030
CHINA

Re: K072739
Trade/Device Name: Sterile Hypodermic Syringe for Single Use With/Without Needle
Retractable Auto-Disable Syringe for Single Use With/Without Needle
Sterile Insulin Syringe for Single Use With Fixed Needle
Sterile Hypodermic Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, MEG, FMI
Dated: March 11, 2008
Received: March 11, 2008

Dear Ms. Hong:

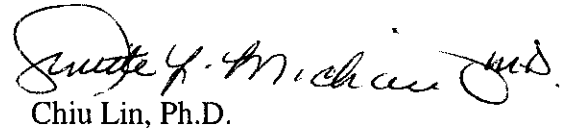
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number: K072739

Device Name: Sterile Hypodermic Syringe for Single Use With/without needle

Indications for Use:

The Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072739

Indications for Use

510(k) Number: K072739

Device Name: Retractable Auto-Disable Syringe for single use With/without needle

Indications for Use:

The Retractable Auto-Disable Syringe for single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072739

Indications for Use

510(k) Number: K072739

Device Name: Sterile Insulin Syringe for single use with fixed needle

Indications for Use:

The sterile Insulin Syringe for single use with fixed needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072739

Indications for Use

510(k) Number: K072739

Device Name: Sterile Hypodermic Needle for single use

Indications for Use:

The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072739